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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,932

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Gerald R. Heller

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

11/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,932	Applicant(s) HELLER ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10-13 and 15-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 7/30/08 has been entered.

Claims 10-13, 15-18 are present for examination.

Claims 1-9, 14 and 19-22 are cancelled.

Terminal Disclaimer

The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because: the terminal disclaimer was not received yet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Donadio, III et al. (US 5,741,429).

Donadio discloses, Figs. 12-13, a catheter system comprising: a guide wire 95; a catheter 20 (col. 6, lines 26-29) including a lumen defining an internal diameter; a catheter 20 including a lumen defining an internal diameter; an adapter (including 96 and 93) selective position able within the lumen of the catheter, the adapter including an external diameter substantially equal to the internal diameter of the lumen of the catheter (col. 16, lines 35-40); the adapter further including a lumen defining an internal diameter; the guide wire accommodated in side the lumen of adapter. Donadio further discloses that his invention can be used as catheter, including guide catheters, balloon catheters, etc...(col. 1, lines 11-17). Therefore, the catheter device in Figs. 12-13 can be used as a balloon catheter. Donadio further shows that the guide wire in Fig. 20 is representative guide wire of his invention; wherein the guide wire having

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two different external diameters along a length. Donadio also suggests that various other guide wire configurations (such as different external diameter) could be employed within the scope of his invention (col. 15, lines 19-20).

As noted that, Examiner interprets the limitation "substantially equal" very broadly. Beside that, since the guide wire varies diameter, therefore, the internal diameter of the lumen of the adapter must be change and substantially equal to the external diameter of the guide wire so that to provide interference fit to supporting, increasing the stiffness, flexibility and prevent kinking during its insertion into the blood vessel (also see col. 1, lines 35-40).

Regarding claim 11, the adapter is removable slidably within the lumen of the catheter.

Regarding claim 12, the adapter extends beyond the length of the catheter, the portion extending beyond the catheter being adjustable by slidably positioning the adapter within the lumen of the catheter (Figs. 12-13).

Regarding claim 13, the portion 93 of the adapter extending beyond the length of the catheter includes a flexible tapered tip (Figs. 12-13).

Regarding claim 18, Donadio discloses the claimed invention except for the lumen of the catheter is about 0.0035 inches and the lumen of the adapter is about 0.018 inches. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the values listed above, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donadio, III et al. (US 5,741,429) in view of Leoffler (US 5,891,154).

Donadio discloses the invention substantially as claimed. Donadio does not disclose the catheter includes a radially expandable stent.

Leoffler discloses a catheter includes a stent 16 positioned about an expandable balloon portion 14. Also, it is well known in medical art, especially in percutaneous transluminal coronary angioplasty (PTCA) that the catheter includes an expandable stent to expand and hold the damaged artery.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Donadio with a stent, as taught by Leoffler, in order to expand and hold the damaged artery.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,692,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of instant claims are fully disclosed and covered by the claims in the Patent No. 6,692,482.

Response to Arguments

Applicant's arguments filed 7/30/08 have been fully considered but they are not persuasive.

1. Applicant argues on page 4 of Remarks filed on 7/30/08 that:

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The Examiner indicated that Donadio discloses "a catheter 20 including a lumen defining an internal diameter ...", making reference to Figures 12-13. The structure identified in Figures 12-13 of Donadio is not a catheter but rather a tubular member that can be incorporated into or otherwise form a catheter introducer. See: col. 16, ll 12-15. As indicated by Donadio, "[c]atheter sheaths and introducers are used to provide a conduit for introducing catheters, fluids or other medical devices into blood vessels." Col. 2, ll 52-54, see also Figure 12. These catheter introducers are typically disposed at the vascular access point and are used as a conduit for passing a treatment device (e.g., a guidewire, catheter, etc.) into the vasculature. The catheter introducer, however, is typically not used to directly treat the vasculature. Instead, catheter introducers provide access or otherwise "introduce" the treatment instrument (e.g., the catheter) into the vasculature.

In response, Donadio clearly states that the element 20 for use as a catheter, guide wire, catheter sheath or drug infusion catheter/guide wire (col. 6, lines 26-28) (emphasis added).

Although, Donadio calls the element 20 is as catheter sheath. The name "catheter sheath" is just a label, and labels, statements of intended use, or functional language do not structurally distinguish claims over prior art, which can function in the same manner, be labeled in the same manner or be used in the same manner. See *In re Pearson*, *Ex parte Minks*, and *In re Swinehart*.

2. Applicant argues that Donadio fails to teach or suggest such a configuration or that the catheter includes an expandable balloon portion.

In response, as discussed in the rejection above, Donadio states that his invention relates to flexible device for use as catheters, including guide catheters and balloon catheters (col. 1, lines 10-15) (emphasis added). Therefore, the device of Donadio can be include or provide a balloon catheter as well.

Conclusion, the device of Donadio meets all the limitation of claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763